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of Asthma Outcomes

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Mid-Term Overall Evaluation Report

PROPOSAL: 1999000148

**TITLE: Effect of Computer Systems and Electronic Communication on Asthma
Outcomes**

1. ACCOMPLISHMENTS:

Notification of the award was received on 25 FEB 00, and work represented in this interim report covers the period up to 1 SEP 00. Since then, great strides have been made towards creating this project de novo. Due to the unique nature of this project, the work to date has been focused on building the infrastructure for the study intervention as well as identification and recruitment of the patient population. Since human subjects are to be enrolled, Institutional Review Board (IRB) approval was necessary prior to moving forward. The application was completed and presented to the committee on 3 March 00. Approval was received on 10 March 2000. Contracts were submitted to the local contracting office for initial computer purchase required to start software development on 15 March. There was an unexpected delay of approximately four weeks with contract being awarded on 12 April and the investigator's computer systems not arriving until 27 April. Once these delays were recognized, a local system was upgraded in order for work to begin on web page and database design. Recognizing that this 6-8 week delay would be repeated with the purchase of the server and patient computer systems, there purchase orders became the highest priority. They were submitted on 1 May 00 and 9 May 00. Despite these challenges and the software developers required attendance at the AMEDD Officer Basic Course, the web page, database, and disease management software are complete including coordination with the Center for Total Access integrating their patient education software. The entire disease management system is currently ready for beta testing. Barriers to beta testing will be discussed further later. In addition to hardware acquisition and software design, effort has been oriented toward patient enrollment and follow-up. The eligible population, consisting of 371 patients, has been identified through CHCS pharmacy data and sorted according to Primary Care Manager (PCM). The content of baseline data acquisition has been collated and incorporated into the database enabling computerized collection of baseline data and facilitating data analysis. A literature search was conducted and validated asthma quality of life questionnaire has been identified and the author contacted. However, obtaining permission for use has been delayed due to the author's relocation to Australia. Investigators have pressed forward in spite of this with the default plan of omission if necessary. Contracts were drafted and submitted for approval to the contracting office for the funded personnel. Again, delays associated with the government contracting process have been encountered. To date one

research assistant has been hired, and hiring actions are pending for a nurse. This has slowed study progress as all administrative work has been performed by the investigators in addition to their regular duties as Army physicians. Significant delays have occurred in server installation. The purchase order was submitted on 9 May 00 with its arrival on 10 JUL 00. Since this time, Information Management Division has required the purchase of a separate software package, reviewed web pages for content, and been working on clearing installation of server with MEDCOM. Several revisions were necessary secondary to the Americans with Disabilities Act requirement. This has prevented the investigation team from beta testing prior to deployment of the system. In spite of these challenges with getting the server on line, the investigation team was able to use one of the purchased computers to act as a local server with local connections. This enabled enrollment of 50 patients and collection of baseline data. This process was again delayed when the investigator designing our software, CPT Suykerbuyk, discovered a problem with Microsoft 2000. Upon seeking assistance, it was learned that Microsoft was unaware of this problem with the software. Therefore, a local patch was created prior to a solution being developed at Microsoft. At the time of the midterm report, enrollment has been halted due to the deployment of Dr. Suykerbuyk in support of the peacekeeping mission in Bosnia. While tremendous efforts were made to avoid this deployment, other mission requirements prevented its avoidance. Therefore, an alternative plan for the study was developed for the second half of project as detailed in #3. Key Research Accomplishments *IRB proposal and approval *Patient consent and contracts created and approved by JAG *Study hardware and necessary proprietary software obtained *Web page designed for patient and provider communication *Central Database designed containing demographic, baseline, and follow-up data points *Disease assessment software designed including compliance queues, data analysis, and feedback for patients and providers *Patient computer system and server acquired. *Patient population identified through CHCS data *Patient enrollment and baseline data commenced with 50 patients enrolled *Employment contracts for administrative assistant and mid-level provider submitted for approval

2. PROBLEMS:

Several problems have been overcome during the first half of the project. Some of these are potentially preventable for future research of the same scope, however the largest problems faced are due to the unique nature of military medicine and the structure of the funding. 1. Deployments. Recognizing the unique position of the military physician is essential when designing research. Unlike other research environments where a grant funds a percentage of the investigator's time, the investigators on this team are all active duty Army physicians who are members of a residency teaching staff. The time and energy required to conduct the research has come in addition to the multiple missions supported by the physicians including supporting readiness, delivery of state-of-the-art patient care, and maintaining a high quality educational environment for residents and students. In addition to patient care and teaching, during the first six months of research, the investigation team has faced multiple military taskings. Two of the core investigators were sent on Field Training Exercises with the 249th Field Support Hospital, and one had to complete his Officer's Basic Course. Additionally, as detailed below, the investigator who has written the study software is currently being deployed in support of the

peacekeeping mission in Bosnia. While immense effort was spent to avoid this deployment, mission requirements, and unanticipated personnel issues mandated it. As physicians and officers in the U.S. Army, deployment in support of national military missions remains our primary mission. Therefore, other missions such as research must remain adaptable to these challenges. Viewing every obstacle as an opportunity, this project continues to adapt to primary mission requirements and find creative ways of continuing research. While delaying beta testing and clinical investigation, the deployment to Bosnia provides the additional benefit of a true deployment test. This will provide further basis for the benefit to the active duty soldier in worldwide deployment when the study is complete.

2. Funding Structure. Funding allocation that is awarded well after the start of the fiscal year yet must be allocated prior the end of the same year sProviding funding for clinical research on the governmental fiscal year leads to a short time lines., but places restrictions on expenditures that lead to significant delays. Contracting regulations secondary to government financing also effectively shorten time lines. These opposing requirements lead to inefficiency and frustration. Fiscal year funding provides a sense of urgency for obligation of funds. However, the local personnel who are required to support such research do not share the urgency and are limited by purchasing and contracting regulations. These regulations lead to delays of 4-8 weeks on purchases. Additionally, inefficiency is created by the funding structure. The obligation or loss of funds half way through the project limits investigator's ability to adjust resource allocation according to challenges which arise during research. In addition, funds are allocated according to estimates of future expenses rather than actual costs. This prohibits realization of potential savings during the second half of the funded period. (saving are not the issue) This limits the ability to adjust to potential unforeseen requirements in the later stages of research. Finally, a close ended reported cycle threatens potentially significant results. While the need for strict accountability for research funds is understood, a restrictive timeline threatens to cause premature closure of studies. This can significantly reduce the DOD return on investment. In the setting of the current research setting, providing a final report before other requirements permit complete clinical testing may reduce the demonstrable benefit from a significant improvement in chronic disease management.

3. Purchasing and Contracting Requirements. As alluded to above, obligation of funds via traditional purchasing requirements significantly delays acquisition of hardware and personnel required to complete research projects. This is potentially avoidable via one of two mechanisms. First, distribution of funds via a secured account against which purchases can be made outside of traditional property management and contracting offices. This would give local control of timing of purchases and vendors to the Primary Investigator providing flexibility to balance potential cost savings and strict time requirements. Alternatively, central contracting support (for example, at TATRC) where time constraints and problems unique to clinical research can be handled. An additional benefit of economy of scale could be realized with a central contracting support office. This would facilitate sharing of solutions to common problems encountered by different researchers resulting in a more efficient research process. If these are not viable solutions, future funding time lines must include these delays in expected time lines. Additionally, investigators should be provided assistance in avoiding these avoidable delays. This would allow proactive steps such as those taken by this investigation group. Once the delays were recognized

during the initial hardware purchase, additional purchase orders were submitted earlier than originally scheduled to allow for contracting delays. 4. Information Management Division. Coordination with IMD has been a recurrent challenge. As new software has been utilized for database and web site creation, local knowledge has been outstripped. This has led to inefficiency in two ways. First of all, the study programmer has had to spend a significant amount of time educating those in IMD about the system and its design. This was necessary in order to gain approval for its installation of research hardware in local facilities.

3. LIFE-CYCLE:

Beta Testing will begin as soon as CPT. Suykerbuyk reaches Bosnia and two computer systems are delivered. This will allow him to use surrogate patients from the staff of the 249th Field Support Hospital to log into the server located at DDEAMC. As problems are identified he will make changes in the code and save onto a CD ROM. This CD will then be shipped back to Ft. Gordon where local installation of the upgrades will occur. While requiring greater resource utilization and time, this will actually serve to test one of the major hypothesized advantages of such a system, which is worldwide deployability, while further software refinement occur. Previously enrolled patients have been contacted and informed of the delay in study due to missions in support of active duty personnel. Upon completion of beta-testing and the Bosnia Mission, patients will be re-contacted, baseline information re-collected, and enrollment completed. This will result in anticipated deployment of the system and data collection beginning in the May – June 01 time frame. Data will be collected in a continuous fashion with analysis on a regular basis until a significant difference is evident or a 6 month study period is complete. At that time, data will be analyzed and reported per the original proposal. Since this time period does not include the major allergy season in this region or the seasons of highest asthma exacerbation extension of data collection for 1 year may be warranted.

4. DELIVERABLES:

The original proposal defined the development, testing, and study of a web-enabled Asthma management tool which has broad applicability across the AMEDD. The system design is currently complete and a field test from Bosnia will be initiated as soon as the hardware is on sight. The results of this test will be reported in terms of challenges met and solutions unique to deployment at the time of the final report due in 3/01. Due to delays previously identified, the final part of the proposal will not be complete until approximately 12/01 with 6-month data. As documented in the original proposal, efficacy during the study will be reported as differences in clinical outcomes such as ED visits and hospitalizations. In addition, patient satisfaction and provider satisfaction with the system as a means of health care delivery will be reported. The AMEDD wide applicability of this project is evident in the efforts and resources being allocated to the implementation of Clinical Practice Guidelines (CPG) across the DOD. This project which can be used beyond asthma is the development of a chronic disease management system and has the potential to overcome major obstacles known to effect CPG implementation and effectiveness